

REMARKS

Summary of Office Action

Claims 1-20 and 29-44 were pending in this application. Claims 1-20 have been withdrawn pursuant to a restriction requirement.

The Examiner finally rejected claims 29-36 under 35 U.S.C. 103(a) as being obvious from Szapiro et al. U.S. Patent No. 6,602,223 (hereinafter "Szapiro") in view of van der Wal U.S. Patent No. 5,569,192 (hereinafter "van der Wal").

Claims 37-44 were finally rejected under 35 U.S.C. 103(a) as being obvious from Szapiro in view of Odell et al. U.S. Patent No. 6,263,641 (hereinafter "Odell").

Summary of Applicants' Reply

Applicants have proposed canceling withdrawn claims 1-20 without prejudice and amending the preambles of claims 29 and 39 and the claim dependency of claim 38, none of which is related to patentability over the prior art.

No new matter has been added.

Reconsideration of this application in view of the following remarks is respectfully requested.

Showing of Good and Sufficient Reasons  
Under 37 C.F.R. § 1.116(b)(3)

Applicants request amendment of this application, even though a final rejection has been issued. The proposed amendments of claims 29, 37, and 39 are unrelated to patentability over the prior art and should therefore not require any additional search or

consideration. Accordingly, applicants respectfully request entry of the proposed amendments and consideration of the following remarks.

Rejections of Claims 29-36 Under 35 U.S.C. § 103(a)

Claims 29-36 were rejected under 35 U.S.C. §103(a) as being obvious from Szapiro in view of van der Wal.

These rejections are respectfully traversed.

Independent claim 29 is directed to a method of loading a medicament-containing chamber of an automatic injection device. In particular, claim 29 requires filling a rear compartment of the chamber with a wet medicament through a rear end of the chamber and filling a front compartment with a dry medicament through a front end of the chamber.

As described in applicants' specification, applicants' chamber advantageously

“has an open mouth configuration wherein the needle-end of the ... chamber is not significantly narrowed or tapered. Such an open mouth configuration permits direct access to the dry portion 152 of chamber 150 for easy loading. Further, the open mouth configuration aids in preventing cross contamination between wet portion 151 and dry portion 152 in that the dry portion does not have to be filled through liquid portion 151 of chamber 150” (page 9, paragraph 39).

Szapiro does not disclose or suggest in any way applicants' method.

Indeed, Szapiro is completely silent with respect to the manner in which its first and second chambers 2,3 are filled. Also, Szapiro is completely silent with respect to the order in which the chambers are filled (*see* applicants' dependent claim 32).

Szapiro's FIGS. 5-9, 12, and 13 show only the structure of its pre-filled syringe and the mixing and discharge sequence of its first and second products 9,10 -- not the loading of those products into their respective chambers.

Applicants' respectfully submit that the Examiner is using impermissible hindsight to state that Szapiro "teaches ... filling the rear compartment (10) with a first medicament, sealing the rear end (via 7), and filling the front compartment (2) with a second medicament and sealing the front end (via 6)" (December 8, 2006 final Office Action, bottom page 2 to top page 3).

Note first that the front end of chamber 2 does not have an open-mouth configuration as in applicants' invention, but instead has an integral, narrowly-tapering passage 18. Although the open end of passage 18 appears to be about three times as wide as the opening in needle 11, that open end is still very small.

Applicants therefore submit that Szapiro's front compartment (i.e., first product chamber 2) was never intended to be filled through passage 18, which, arguably at best, is ill-suited for such a task.

And moreover, in addition to Szapiro's silence, applicants further submit that a person of ordinary skill in the art would not be motivated in any way to load a medicament through narrow passage 18 in view of the much larger opening at the rear end of Szapiro's chamber.

If the Examiner continues to assert that Szapiro "teaches" filling first product chamber 2 through passage 18, applicants respectfully request the Examiner to cite evidence -- other than applicants' own teachings -- to show why a person of ordinary skill in the art would be motivated to use such an impractical, if not impossible, method of filling that chamber when filling from the larger rear opening is such an obvious alternative.

Accordingly, Szapiro does not meet the “filling the front compartment ... through a front end of the chamber” limitation of claim 29.

Furthermore, Szapiro does not meet the “filling the front compartment ... with a dry medicament” and the “filling the rear compartment ... with a wet medicament” limitations of claim 29.

Although Szapiro does not expressly disclose, as the Examiner acknowledged, that one of first and second product chambers 2,3 contains a liquid and the other contains a solid, Szapiro’s FIGS. 5-9, 12, and 13 appear to show that first product chamber 2 contains a liquid, while second product chamber 3 contains a solid. Note also that Szapiro teaches that “as the plunger 7,8 is drawn back .... the product in product chamber 2 ... [is] drawn ... into second product chamber 3” (column 3, lines 59-66), and that cooperative valve member 5 has “a fluid passage 15” (column 3, lines 26; emphasis added), and that the graphic symbol used to denote the contents of first chamber 2 is substantially identical to the symbol for a liquid pursuant to MPEP § 608.02(IX).

Accordingly, applicants’ submit that drawing a liquid from first product chamber 2 into second product chamber 3, which contains a solid, is readily apparent from Szapiro.

Applicants further submit that a person of ordinary skill in the art would not in any way be motivated to reverse the contents of the first and second chambers 2,3, because drawing a solid material from first chamber 2 through fluid passage 15 into second chamber 3 instead of a liquid would be far more difficult and far less effective in mixing the two components in second chamber 3 as taught by Szapiro.

Therefore, Szapiro does not teach “filling the front compartment ... with a dry medicament” and “filling the rear compartment ... with a wet medicament” and, accordingly, does not meet these two limitations of claim 29.

van der Wal was cited to show that a two chamber injection device can have one chamber filled with a solid while the other is filled with a liquid. However, at least because of the manner in which Szapiro’s syringe operates, van der Wal does not make up for the deficiencies of Szapiro.

Lastly, applicants respectfully point out that “simplicity alone is not determinative of obviousness” (Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998)) and that “the very ease with which the invention can be understood may prompt one to ‘fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.’” In re Dembiczak, 50 USPQ2d 1614 (Fed. Cir. 1999) quoting W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983).

In sum, independent claim 29 is not obvious from the combination of Szapiro and van der Wal and should be allowable.

For at least these reasons, dependent claims 30-36, which depend either directly or indirectly from independent claim 29, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 29-36 under 35 U.S.C. §103(a) be withdrawn.

Rejections of Claims 37-44 Under 35 U.S.C. § 103(a)

Claims 37-44 were rejected under 35 U.S.C. 103(a) as being obvious from Szapiro in view of Odell.

These rejections are respectfully traversed.

For at least the same reasons as discussed above regarding independent claim 29, dependent claims 37 and 38, which depend directly and indirectly from claim 29, respectively, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

And for at least these same reasons, independent claim 39, which also requires “filling the rear compartment of the chamber with a wet medicament portion” and “filling the front compartment of the chamber with a dry medicament portion through a front end of the chamber” is also not obvious from Szapiro.

Odell purportedly discloses methods of manufacturing drug delivery and drug container devices in clean, substantially particular-free areas and, accordingly, does not make up for the deficiencies of Szapiro.

Thus, the combination of Szapiro and Odell does not render independent claim 39 obvious and, therefore, claim 39 should be allowable.

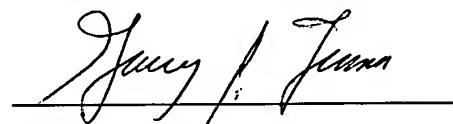
For at least these reasons, dependent claims 40-44, which depend from independent claim 39, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 37-44 under 35 U.S.C. §103(a) be withdrawn.

Conclusion

The foregoing demonstrates that claims 29-44 are allowable. This application is therefore in condition for allowance. Reconsideration, entry of the proposed amendments, and allowance are accordingly respectfully requested.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Garry J. Tuma", is written over a horizontal line.

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